Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
DUD101-2WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/DE2004/000839	16.04.2004	17.04.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant		
DUDA, Georg, N.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 20 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 10 sheets, as follows:

      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☒ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DE2004/000839

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1-16 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 2-5,7-22 received by this Authority on 11.05.2005 with letter of 11.05.2005

nos.* 1,6 received by this Authority on 04.07.2005 ( )

☒ the drawings:

sheets 1/6-6/6 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☒ the claims, nos. 1

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DE2004/000839

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-22	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-22	NO
Industrial applicability (IA)	Claims	1-22	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

1 This report makes reference to the following documents:

D1: XP002324307
Babisch J et al: "Biomechanisch fundierte Hüftoperationsplanung mit Hilfe des Softwaremoduls EndoMap" ELECTROMEDICA, Vol. 70, No. 1, 2002, pages 39-46, SIEMENS AG, Berlin, Germany

D2: XP008045570
Blumentritt S: "Die Beziehung zwischen dem Gang des Menschen und dem Hüftgelenkaufbau in der Frontalebene" GEGENBAURS MORPHOLOGISCHES JAHRBUCH, Vol. 136, No. 6, 1990, pages 677-693 ISSN: 0016-5840

D3: XP002324308
Techtran Ltd.: "Osteotomy Analysis Simulation System; OASIS - A Boon to Osteoarthritis Patients" JAPAN HEALTH CARE INDUSTRY NEWS - NEWS CLIPS FROM INDUSTRY PAPERS, [Online] November 1998 (1998-11), pages 1-3, retrieved from

the Internet:
URL: http://www.techtran.co.jp/techtr_e/healthcare/199811.html>
[retrieved on 2005-04-11]

D4: XP008045554
Bergmann G et al.: "Hip contact forces and gait patterns from routine activities"
Journal of Biomechanics, Vol. 34, No.7 (July 2001), pages 859-871; Elsevier, UK; ISSN 0021-9290

D5: XP008045615
Heller M O et al.: "Musculo-skeletal loading conditions at the hip during walking and stair climbing"
Journal of Biomechanics, Vol. 34, No. 7 (July 2001), pages 883-893; Elsevier, UK; ISSN 0021-9290

D6: XP000962400
http://www.innovations-report.de/html/berichte/messenachrichten/bericht-6124.html
Internet press release from Siemens AG on 20 November 2001

2 INVENTIVE STEP

The present application does not meet the requirements of PCT Article 33(1), because the subject matter of claims 1-22 does not involve an inventive step within the meaning of PCT Article 33(3).

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2.1 Claims 1 and 20

2.1.1 D1 discloses:

a method for simulating musculoskeletal strains on a patient in order to prepare surgical interventions,

(see D1, for example pages 42-43: "The planning of the hip endoprosthesis implantation consists of the following individual steps: [...] → individual steps 1 to 9)

involving the following steps:

a. The determination of individual musculoskeletal parameters of the patient by measuring anthropometric parameters and the position and orientation of joints;

(see D1, pages 42-43, individual steps 2 and 3: body size, weight, and the 10 auxiliary points on the pelvis and femur contour constitute the anthropometric parameters measured in claim 1, i.e. the individual musculoskeletal parameters of the patient);

b. automatic determination of the individual musculoskeletal strains from the determined musculoskeletal parameters of the patient;

(see D1, page 42, individual step 3: "[...] pre-operative analysis of the

current state";

- for a definition of the "biomechanical analysis", see the section entitled "Theoretical Basis" on page 40, in particular the fourth paragraph:

"An interesting alternative is offered by Blumentritt's model, which conducts a biomechanical analysis of the hip joint [...] at the moment of maximum strain during fast walking [...]. Experiments [...] led to the definition of 5 model-specific parameters [...]".

The "model-specific parameters" mentioned in D1 do not correspond to the measured musculoskeletal parameters defined in claim 1, step a. They are defined in table 1 in conjunction with figure 2 on page 41: these parameters mostly relate to strengths and directions of forces which are interpreted as the individual musculoskeletal strains defined in claim 1, step b. The last sentence of the fourth paragraph on page 40 discloses the automatic determination of these strains (= "parameters" in D1) from the measured anthropometric parameters body size, weight, and auxiliary points: "The parameters are calculated...";

d. computer-assisted evaluation of the individual musculoskeletal strains with respect to at least one target criterion.

(see D1, pages 42-43: individual steps 4 to 7: the "ideal value of 12 points" for the BLB Score, for which table 1 indicates the calculation using the determined strains, is a target criterion used to evaluate the calculated strains. Each parameter interval in table 1 is, per se, also a target criterion).

2.1.2 Step "c" in claim 1 is not disclosed in D1, i.e. that:

c. for the automatic determination of the individual musculoskeletal strains, the individual or varied musculoskeletal parameters are compared to musculoskeletal reference parameters stored in a database, musculoskeletal reference strains that correspond to the musculoskeletal reference parameters being determined as the individual musculoskeletal strains, the musculoskeletal reference parameters being stored in the database as discrete values and the musculoskeletal reference parameters being compared to the

individual musculoskeletal parameters by means of functional correlations, in particular by means of interpolation.

Step c describes the use of a table (LUT, or Look-Up Table) for defining the strains corresponding to the measured parameters, whereby intermediate values can be interpolated therefrom.

Although D1 does not disclose this specific embodiment for calculating strains, a determination
- through said table/LUT
- or though direct functional calculation using a model function are standard ways to determine the strain values from the measured parameter values. Both ways of converting input values (here, the individual parameters) into output values (here, the individual strains) are obvious to the average computer expert and are routinely implemented, depending on the amount of memory or computing power available. Calculation using a table is a measure that is regarded as saving on calculation time but eating up memory, and, conversely, a direct functional calculation is regarded as memory saving but intensive in terms of calculation.

Even if it were assumed that D1 involves a

direct functional calculation (according to the Blumentritt model), a person skilled in the art would obviously consider, especially if there were low computing power, using a table calculation in order to accelerate the calculations, whereby the implementation, in order to save on memory, of a table having few node values, involving intermediate value interpolation, is a standard measure.

Therefore, claim 1 and, for the same reasons, the corresponding device claim 20 do not involve an inventive step.

2.1.3 The **optional features of claim 1, step a.** relate to:

- the automation of anthropometric parameter measurement: the automation of measurements in digital X-rays is very widespread in medical image processing and is, to a person skilled in the art, an obvious option if an advantage can then be derived from the automation, in particular with respect to a required degree of precision or speed in processing; and

- the use of the simulation of musculoskeletal strains in systems in computer-assisted surgery or surgical navigation: D1 describes the use of the described algorithm in combination with such systems *(see D1, page 45, left-hand column starting on line 16: "We consider that, in combination with the [...]*

navigation of the hip endoprosthesis implantation in the CT image, a supplementary two-dimensional frontal biomechanical analysis definitely makes sense [...]").

The use of the optional features of step a in claim 1 therefore does not involve an inventive step.

2.1.4 The **optional features of claim 1, step d** relate to the various target criteria that should be taken into consideration depending on the type of operation, including for non-computer-assisted operation planning. It is obvious for a person skilled in the art to consider them in a manner dependent on the situation in computer-assisted operation planning, and therefore taking said criteria into consideration does not involve an inventive step.

2.2 The additional features of **claim 2** are disclosed in D1

(see D1, page 42, individual step 5: the evaluation of different rotational centers of the prostheses according to the BLB score implicitly discloses the additional features of claim 2).

Therefore, claim 2, in conjunction with the line of reasoning in point 2.1, does not involve an inventive step.

2.3 D1 partially discloses the additional features of **claim 3**.

D1 discloses that:

- steps e to g are repeated

(see D1, page 42, individual step 5: the evaluation of different rotational centers of the prostheses according to BLB score implicitly discloses the additional features of claim 3).

As is indicated later in claim 3 (but not explicitly disclosed in D1), the repetition of steps e to g until

- a predetermined target value is reached for at least one target criterion

serves to limit the number of calculations to be carried out and is, to a person skilled in the art, an obvious adaptation of the method described in D1 to specific circumstances, such as a low processing capacity or time constraints.

Therefore, in conjunction with the line of reasoning in points 2.1 and 2.2 relating to claims 1 and 2, claim 3 does not involve an inventive step.

2.4 D1 partially discloses the additional features of **claim 4**. D1 discloses that:

- the musculoskeletal parameters corresponding to the target value are

output on an output device and stored in a storage device

(see D1, page 42, individual step 5, and figure 3c: the output - and inherent storage - of a "light cloud of dots", i.e. of the rotational centers having the "ideal" BLB Score).

The additional features that relate to the transfer of these parameters to a computer-assisted surgical program and cannot be derived from D1 do not involve an inventive step, because they are an obvious component of the integration of the method or the device from D1 into these systems *(see also point 2.1.3 of this report)*.

Therefore, in conjunction with the line of reasoning in points 2.1 to 2.3 relating to claims 1 to 3, claim 4 does not involve an inventive step.

2.5 The additional features of **claims 5 and 6** are disclosed in D1 *(see D1, page 41, "Practical Planning Implementation", in particular the third paragraph)*.

Therefore, in conjunction with the line of reasoning in points 2.1 to 2.4 relating to claims 1 to 4, claim 5 does not involve an inventive step.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2.6 The additional features of **claims 7-9 and 11** are disclosed in D1 *(see D1, page 40, "Theoretical Basis", and in particular the fourth paragraph;*
Observation with respect to claim 9: the selection in D1 of the Blumentritt model for the biomechanical analysis of the hip joint inherently constitutes an adaptation along the lines of claim 9).

Therefore, in conjunction with the line of reasoning in point 2.1 relating to claim 1, claims 7-9 and 11 do not involve an inventive step.

2.7 The additional features of **claim 10** are not explicitly disclosed in D1. It is known, however, that the ENDOMAP software module, in which includes the algorithm for hip operation planning presented in D1, is also intended for use in knee operation planning. *(see, for example, D6, second paragraph: "Siemens presents [...] a computer program that plans a hip or knee operation using digital images of the patient.")*
Therefore, the inclusion of the possibility of a knee operation in ENDOMAP means that the user of the method described in D1 necessarily has to select the biometric-mathematical Blumentritt model (from a database) that corresponds to the body part to be operated on

(here, a hip rather than a knee), and that this selection is made in an inherent manner based on the individual musculoskeletal (hip) parameters determined.

Therefore, in conjunction with the line of reasoning in points 2.1 and 2.6 relating to claims 1 and 7-9, claim 10 does not involve an inventive step.

2.8 D1 discloses the additional features of **claims 12 and 13** *(see D1, page 43, individual step 8, and figure 3 or 4)*.

Therefore, in conjunction with the line of reasoning in point 2.1 relating to claim 1, claims 12 and 13 do not involve an inventive step.

2.9 The additional features of **claim 14** relating to the use of the method in claim 1 for evaluating and controlling a patient's rehabilitation process are obvious to a person skilled in the art.

Furthermore, D2, for example, indicates *(see D2, page 679, penultimate sentence in the section "1. Introduction")* *"that knowledge of the natural anatomical rules of formation is the precondition for understanding [...] therapeutic processes in the hip joint".*

D3, which discloses the ZONA-OASIS software for the pre-operative simulation of strain in the knee joint, states (see D2, page 2, lines 7-8): *"Being capable of predicting the outcome of the surgery, the system allows the physician to use the display for recommending treatments suitable for the patient."*

Therefore, claim 14 does not involve an inventive step.

2.10 D1 discloses the additional feature of **claim 15** *(see D1, pages 42-43, individual steps 2 and 3: body size, body weight, and the 10 auxiliary points on the pelvis and femur contour constitute the anthropometric parameters measured in claim 1, i.e. the individual musculoskeletal parameters of the patient).*

Therefore, in conjunction with the line of reasoning in point 2.1 relating to claim 1, claim 15 does not involve an inventive step.

2.11 The additional features of **claim 16** do not involve an inventive step.
- With respect to the feature of automatic measurement, see point 2.1.3 of this report;
- with respect to the feature of computer tomography, see D1, page 45, left-hand column, lines 7-9: "[...] in certain cases, an additional 3D-CT analysis is useful [...]";

- with respect to the feature of the motion sensors: see point 2.12 of this report.

2.12 The additional features of **claims 17 and 18** relate to the determination of individual gait parameters for the automatic determination of individual strains.

D1 makes reference to the biomechanical-mathematical Blumentritt model disclosed in D2 (reference sign [25] in D1). As described in D2, the Blumentritt model is established based on a gait parameter analysis of 35 individuals *(see D2, section 2.3.2)*. D1 takes dynamic parameters into consideration in the following manner *(see D1, page 40, "Theoretical Basis", fourth paragraph)*:

> *"An interesting alternative is offered by Blumentritt's model, which carries out a biomechanical analysis of the hip joint [...] at the moment of maximum strain during fast walking [...]. Experiments [...] led to the definition of 5 model-specific parameters [...]".*

It is obvious to a person skilled in the art that the restriction in D1 of the model calculations to the moment of maximum strain cannot perfectly reflect the individual musculoskeletal strains of a patient, and that it seems at least desirable to have a strain model for the entire cycle of movement

(and also for different types of movement), and, in conjunction therewith, the necessary determination of the individual gait parameters of a patient as described in claims 17 and 18.

Furthermore, a person skilled in the art is familiar with such a model from D4 and D5. *D4, page 860, left-hand column, second and third paragraphs, states:*

> *"The goal of this study was to create a unique data base of hip contact forces and simultaneously measured gait data [...]. The obtained gait data was used as an input for a muskulo-skeletal model to calculate muscle forces [reference to D5] [...]. Their model can [...] be used to investigate clinical problems like muscle deficiencies or operative procedures."*

Therefore, claims 17 and 18 do not involve an inventive step. The same applies to device **claim 21**, which relates to a movement analysis system.

2.13 D1 discloses the additional features of **claim 19** *(see D1, page 45, left-hand column starting on line 16: "We consider that, in combination with the [...] navigation of the hip endoprosthesis implantation in the CT*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

image, a supplementary two-dimensional frontal biomechanical analysis definitely makes sense [...]"). Therefore, in conjunction with the line of reasoning in point 2.1 relating to claim 1, claim 10 does not involve an inventive step. The same applies to device **claim 22**, which relates to a navigation system.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Box I

This report was established without taking into consideration the amended claim 1 submitted on 4 July 2005, because said claim goes beyond the disclosure of the application as originally filed (PCT Rule 70.2(c)).

The claim 1 amended on 4 July 2005 involves the change (in line 15) of the word "wherein" to "and". This amendment causes step c to be interpreted as being separate from step b. In contrast, when "wherein" is included in the wording of the claim submitted on 11 May 2005, step c is regarded as an embodiment of step b.

The interpretation of steps b and c as separate steps goes beyond the original disclosure of the application, since in the original application, the features of step c are included exclusively as an embodiment of step b. The relevant passages are:

- page 6, line 21 to page 7, line 17
- page 13, lines 3-8
- original claims 1, 7 and 10.

It is clear from these passages that the wording "determination of the [...] strains" in step b was selected in order to cover two variants of the embodiment, namely a

Supplemental Box

"determination", either through the features of step c (original claim 7) or through a "calculation" of the strains (original claim 10).

Therefore, the following relates to the claims submitted with the letter of 11 May 2005, taking into consideration the correction of claim 6 made on 4 July 2005.